UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WISCONSIN

PROMEGA CORPORATION,

Plaintiff,

and

MAX-PLANCK-GESELLSCHAFT zur FORDERUNG der WISSENSCHAFTEN E.V.,

Case No. 10-cv-281-bbc

Involuntary Plaintiff,

v.

LIFE TECHNOLOGIES CORPORATION, INVITROGEN IP HOLDINGS, INC., and APPLIED BIOSYSTEMS, LLC,

Defendants.

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO PRECLUDE TESTIMONY OF DR. RANDALL DIMOND REGARDING STR KIT USE BY INSTITUTION TYPE

Defendants Life Technologies Corporation, Applied Biosystems, LLC, and Invitrogen IP Holdings, Inc., (collectively, "Life"), by and through counsel, respectfully submit this Memorandum in Support of their Motion to Preclude Testimony of Plaintiff Promega Corporation's ("Promega's") proffered expert Dr. Randall Dimond.

I. INTRODUCTION

Promega's alleged expert Dr. Randall Dimond has proffered opinion testimony that is based only Dr. Dimond's own say-so. Specifically, Dr. Dimond has proffered an opinion about inferring an entity's STR kit use based only on the entity's institution type and has provided absolutely no methodology by which he reached his conclusion. But witnesses cannot provide expert testimony without establishing the opinions are based on an appropriate scientific methodology. Under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), the Court should refuse to admit any testimony by Dr. Randall Dimond on this subject because his methodology is not scientifically reliable. *See Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010).

II. STATEMENT OF THE FACTS

1. This is a lawsuit for patent infringement brought by Promega against Life. (Second Am. Compl. ¶¶ 170-199.) The patents asserted in this lawsuit are referred to as the "Promega Patents."

2. Prior to this lawsuit, Promega had licensed the Promega Patents to Defendants in specified fields in a cross license ("the 2006 Cross-License").

3. The Court has ruled that applications of "chimerism in the context of bone marrow transplant monitoring, cell line authentication, classifying molar specimens and determinations of fetal sex" performed by accused products are not within the scope of the 2006 Cross-License. (November 29, 2011 Opinion and Order, Dkt. No. 345, at 23-25.) The Court

thus granted "plaintiff's motion for summary judgment with respect to direct infringement of the asserted apparatus claims in the '235, '598, '660, and '771 patents" as to sales of "AmpFℓSTR® Amplification Kits" ("AmpFℓSTR® Kits") made by Applied Biosystems LLC ("AB") into the fields of use listed above. (*Id.* at 25.)

A. BACKGROUND OF THE TECHNOLOGY AT ISSUE

4. The AmpFℓSTR® Kits can be used in methods for amplifying and detecting DNA sequences called "short tandem repeats" ("STRs"). DNA provides the blueprints for life by dictating the structure, function, and appearance of all of the cells and tissues in an organism. A nucleotide is the simplest unit of DNA. Generally speaking, DNA is comprised of four different nucleotides, often referred to by the shorthand "A," "C," "G," and "T," linked together in a long chain. It is the sequence of these nucleotides in a particular DNA chain that differentiates the DNA of different organisms, and even of different individuals.

5. STR sequences are regions of DNA that contain repeats of particular nucleotide sequences. For example, the sequence A-T-T may be repeated a number of times in a row (*i.e.,* in tandem) to create a sequence such as A-T-T-A-T-T-A-T-T-A-T-T. The number of times the short sequence repeats in an STR can vary widely in the genomes of different individuals. For example, one individual may repeat a particular short sequence 11 times, and another individual may repeat it 14 times. There are typically many separate STRs in an organism's DNA that could be used to compare the DNA of different individuals. By looking at multiple STRs, individuals can be distinguished from one another. The ability of STR sequences to compare DNA from different individuals and to distinguish between them makes STRs a good tool for determining parentage or paternity, authenticating cell lines, and determining chimerism in bone marrow transplant monitoring, among other uses.

B. PROMEGA'S PURPORTED EXPERT REPORTS

6. In an effort to prove damages for any AmpFℓSTR® Kits that were sold without authorization by Applied Biosystems, LLC and/or Life Technologies, Inc. (collectively, "Life Tech") and used by Life Tech's customers in fields that the Court has ruled are outside the scope of the 2006 Cross-License, Promega has filed reports under Federal Rule of Civil Procedure 26(a)(2)(B) by two alleged experts. These reports attempt to support an alleged damages sales base – that is, they attempt to identify how many AmpFℓSTR® Kits AB purchased from Life Tech were used by Life Tech's customers in fields scope of the parties' 2006 cross-license agreement as interpreted by the Court (chimerism in the context of bone marrow transplant monitoring, cell line authentication, classifying molar specimens, and determinations of fetal sex).

7. One of Promega's two alleged experts is Promega's own Chief Technology Officer, Dr. Randall Dimond, who filed his report on October 21, 2011, (Dkt. No. 316).

8. Dr. Dimond opines, inter alia, that the likely use of human STR kits, such as forensic, paternity testing, or clinical diagnostics, can be determined by a purchaser's institutional type. (Dimond Report, Dkt. No. 316, at pp. 25-29; Dimond Report Exhibit 1, Dkt. No. 316-1.) Specifically, section E and Exhibit 1 of Dr. Dimond's opinion consists of a listing of various types of institutions, such as university, private hospital, government, etc., with Dr. Dimond's corresponding opinion as to whether that institution would or would not be likely to engage in uses inside and/or outside the scope of the 2006 Cross-License.

9. Dr. Dimond does not disclose any methodology that he employed to reach his conclusions. (*Id.*) Instead, he only states that "[t]his opinion is based on my knowledge and experience." (*Id.* at p. 25.)

10. In forming his opinion, Dr. Dimond did not consider Life Tech's customers' actual uses, and instead based his opinion, in part, on Promega's customers' uses. (Dimond Report, Dkt. No. 316 at pp. 25-26.) Moreover, despite the heading "Facts supporting the Opinion," Dr. Dimond does not identify any institution or any institution's actual use of STR kits. (Dimond Report, Dkt. No. 316, at pp. 26-29.) Instead, Dr. Dimond speculates regarding institutions' uses, and, for each institution-type listed in the report, states what use he believes "would be expected" for that institution. (*Id.*) For example, Dr. Dimond states that universities "***would be expected*** to use human STR kits mainly for Research and Cell Authentication applications." (Dimond Report, Dkt. No. 316, at p. 26 (emphasis added).)

11. Dr. Dimond does not address the fact that many universities, both in the United States and elsewhere, have forensic teaching or training centers, or otherwise perform forensic work, such as the University of North Texas. *See* Supplemental Expert Report of John C. Beyer, Docket No. 352, ¶¶ , 12 & 13.

III. ARGUMENT

A. APPLICABLE LEGAL STANDARDS

"The admission of expert testimony is governed by Federal Rule of Evidence 702 and the principles outlined in *Daubert*." *Bielskis v. Louisville Ladder, Inc.*, No. 10-1194, 2011 U.S. App. LEXIS 23089, at *11 (7th Cir. Nov. 18, 2011) (citing Fed. R. Evid. 702; *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147-49 (1999) (extending application of *Daubert* factors to non-scientific experts)). "Under Federal Rule of Evidence 702 and *Daubert*, the district court must engage in a three-step analysis before admitting expert testimony," which consists of determining "[1] whether the witness is qualified; [2] whether the expert's methodology is scientifically reliable; and [3] whether the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue." *Myers v.*

Ill. Cent. R.R. Co., 629 F.3d 639, 644 (7th Cir. 2010) (citation omitted). "The proponent of [an] expert bears the burden of demonstrating that the expert's testimony would satisfy the *Daubert* standard." *Lewis v. CitGo Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009) (citing Fed. R. Evid. 702 advisory committee's note (2000 Amends.)).

In assessing an expert's methodology, the Court "must rule out subjective belief or unsupported speculation." *Deimer v. Cincinnati Sub-Zero Prods, Inc.*, 58 F.3d 341, 344 (7th Cir. 1995) (internal citations omitted); *Lewis v. CitGo Petroleum Corp.*, 561 F.3d 698, 706 (7th Cir. 2009). "[Q]ualifications alone do not suffice. A supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based on some recognized scientific method and are reliable and relevant under the test set forth by the Supreme Court in *Daubert*." *Clark v. Takata Corp.*, 192 F.3d 750, 759 n.5 (7th Cir. 1999); *Lewis*, 561 F.3d at 705 (citation omitted). Indeed, "[a]n opinion without foundation is inadmissible." *The First Years, Inc. v. Munchkin, Inc.*, 575 F. Supp. 2d 984, 995 (W.D. Wisc. 2008) (citing *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert")).

Rule 702 directs that "[i]f the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and ***how that experience is reliably applied to the facts***." Fed. R. Evid. 702, Advisory Committee Notes (emphasis added) (quotations and citation omitted). Indeed, "[t]he trial court's gatekeeping function requires more than simply taking the expert's word for it." *Id*. Thus, the Court considers whether the proffered expert's theory can be and has been tested; whether the theory has been subjected to peer-review and publication; and

whether the theory has been "generally accepted" in the scientific community. *Ervin*, 492 F.3d at 904 (citing *Daubert*, 509 U.S. at 593-94); *Schmude*, 550 F. Supp. 2d at 851.

Notably, the Seventh Circuit has upheld exclusion of expert testimony where the proffered testimony was "merely subjective opinion, lacking any scientific methodology," because the expert "failed to substantiate his opinion on the basis of any scientific research," but only "proffered unverified statements that were unsupported by any scientific method." *Deimer v. Cincinnati Sub-Zero Prods., Inc.*, 58 F.3d 341, 343-44 (7th Cir. 1995). This is because "this type of unsubstantiated testimony plainly provides no basis for relaxing the usual first-hand knowledge requirement of the Federal Rules of Evidence on the ground that the expert's opinion has a reliable basis in knowledge and experience of his discipline." *Id.* at 344.

B. DR. DIMOND FAILS TO PROVIDE A FOUNDATION FOR HIS OPINION THAT USE OF STR KITS MAY BE INFERRED BY INSTITUTIONAL TYPE

Dr. Dimond opines that the nature of a customer's STR kit use can be determined by that customer's institution type. He thus provides his expectation of use according to the institution type. He does not provide any methodology he applied to reach this conclusion. Dr. Dimond essentially would ask the jury to believe that, because he says it is so, he can infer the type of STR kit use by a customer merely by knowing what type of institution the customer is.

Dr. Dimond's opinion lacks foundation and is based solely on his own speculation rather than on any recognized methodology. Instead of linking his opinion to any specific experience with different institutions or to actual institutions and their use of STR kits, Dr. Dimond simply bases his opinion for each institution type on what "would be expected" from that particular institution type. (St. of Facts, ¶ 8.) He provides no indication that he ever engaged in a systematic study of STR kit use by institution type. Moreover, Dr. Dimond relies on his anecdotal expectations regarding ***Promega's*** customers' uses to form his opinion, not Life

Tech's customers. Dr. Dimond does not know the identity of the majority of Life Tech's customers, much less those customers' uses of kits, and has not indicated that he conducted an appropriate scientific study of uses in the industry. As such, Dr. Dimond's opinion is not based on a reliable methodology, but instead amounts to a bare assertion that rests solely on his own authority. This is exactly the type of unreliable methodology that the Court should exercise its gatekeeping role to exclude.

Because Dr. Dimond's opinion is speculative and lacks foundation, it will not help the jury determine how Life Tech's customers use the STR kits. Therefore, the Court should preclude Dr. Dimond from offering an opinion regarding the nature of a customer's STR kit use based on that customer's institution type. *Deimer v. Cincinnati Sub-Zero Prods, Inc.*, 58 F.3d 341, 343-44 (7th Cir. 1995) (upholding exclusion were a proffered expert "failed to substantiate his opinion on the basis of any scientific research," but only "proffered unverified statements that were unsupported by any scientific method.")

IV. CONCLUSION

In light of the foregoing, Defendants respectfully request that the Court preclude Dr. Randall Dimond from offering expert testimony regarding inference of STR kit use based on institution type.

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By: /s/ Francis M. Wikstrom

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